

## REMARKS

Before entry of this Amendment, claims 1 – 9 and 12 – 25 were pending in the application. After entry of this Amendment claims 1 – 9 and 12 – 25 remain pending under examination. The number of total claims has not been increased, and the number of independent claims has not been increased beyond the number for which payment previously had been made.

Applicant has carefully considered the Examiner's Action of April 15, 2010, and the references cited therein. The following is a brief summary of the Action. Claims 1-6, 13, 21 and 22 were rejected under 35 U.S.C. 102(b) as being anticipated by Williamson, IV (USP. 5,545,179). Claim 7 was rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV. Claims 8, 9, 12 and 23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV in view of Kieturakis (USP 5,667,479). Claim 14 was rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV in view of Haber et al (USP 4,850,953). Claims 16-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV and Kieturakis and further in view of Haber et al. Claim 15 was rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV in view of Mulhauser et al (PGPub 2003/0181879). Claims 19 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV, Kieturakis, and Haber et al, and further in view of Salama (USP 6,527,755). Claims 24 and 25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV and Kieturakis, and further in view of Kim (USP 5,569,216).

For the reasons explained below, applicant respectfully traverses the rejection of claims 1-6, 13, 21 and 22 under 35 U.S.C. 102(b) as being anticipated by Williamson.

Lines 1-2 of paragraph 5 on page 2 of the April 2010 Office Action contend that Williamson “teaches a closing system for a natural or artificial anus”. However, this statement is inaccurate, and Williamson in fact never mentions the word anus or the word anal. Column 1, lines 5 – 9 of Williamson explain:

This invention relates to an assembly for use during endoscopic surgical procedures. More specifically, it relates to access an assembly which provides a sealed passageway for the insertion and withdrawal of surgical instruments during endoscopic surgery.

While the present invention pertains to a closing system for a natural or artificial anus, Williamson discloses an endoscopic access assembly 20 through which a surgical instrument 24 (FIG. 11) can be delivered through the body wall 21 of a patient. The difference is not one of mere semantics. The Williamson device is always going to be inserted through a man-made incision that a surgeon carefully makes in the patient and that is carefully calculated as to its location on the patient’s body and as to its predetermined dimensions. Applicant’s device is always going to be inserted through either a natural anus or an artificial anus. As to the natural anus, applicant’s device must be capable of contending with numerous shapes and sizes. As to the artificial anus, applicant’s device must be capable of contending with different locations as well.

Applicant’s only independent claim, claim 1, requires:

a first cylindrical sleeve defining a first lumen with a first diameter and a second cylindrical sleeve defining a second lumen with a second diameter, said second sleeve having a portion nesting within the first lumen of said first sleeve, an inflatable balloon having a generally toroidal structure formed of a hose segment \* \* \* and defining a first end and a

second end, which hose segment is inverted into itself, whereby its two ends extend generally coaxially with each other and said first end is connected to said first sleeve and forms a continuous pathway with said first lumen and said second end is connected to said second sleeve and forms a continuous pathway with said second lumen.

Lines 2-24 of paragraph 4 on pages 2-3 of the April 2010 Office Action contend that Williamson discloses (emphasis added):

a first cylindrical **outer sleeve** (figure 5, **item 25**) defining a first lumen with a first diameter (figure 5, item 31) and a second cylindrical **inner sleeve** (figure 5, **item 27**) defining a **second lumen** with a second diameter (figure 5, item 44) and **comprising an air channel (figure 6, item 38)**, said second sleeve having a portion nesting within the first lumen of said first sleeve (figures 5 and 6), an inflatable thin-walled polyurethane (column 5, lines 42-44) **balloon** (figure 5, **item 26**), preformed with two connection ports or ends (figure 6, **items 34 and 35**), having a generally toroidal structure, formed of a hose segment with a two-dimensional surface and defining a first and a second end, which hose segment is inverted into itself to define an inner wall and an outer wall and wherein the portion of the inner wall of the inflated balloon disposed internally of the wearer defining an internal area configured without any rigid guide shaft therein that otherwise might project into the wearer's intestine (figure 6), whereby its two ends extend generally coaxially with each other and said first end is connected to said first sleeve (figure 6) and forms a continuous pathway with said first lumen and said second end is connected to said second sleeve and forms a continuous pathway with said second lumen;

However, the above attempt of the April 2010 Office Action to read claim 1 limitations on the structure illustrated in Williamson FIGs. 5 and 6 is flawed. As noted above, the April 2010 Office Action says that item **25** (rigid base) shown in Williamson FIG. 5 constitutes the **first** cylindrical outer **sleeve** of applicant's claim 1 with a first lumen. The April 2010 Office Action says that item **27** (rigid cap) shown in Williamson FIG. 5 constitutes the **second** cylindrical inner **sleeve** of applicant's claim 1. The April

2010 Office Action says that item 26 (elastomeric sealing element) shown in Williamson FIG. 5 constitutes the inflatable thin-walled polyurethane **balloon** of applicant's claim 1 having a generally toroidal structure with a **first end** that is **connected to the first sleeve (figure 6)** and forms a continuous pathway with said first lumen and a **second end is connected to said second sleeve** and forms a continuous pathway with said second lumen.

Thus, the April 2010 Office Action contends that the first end of the Williamson balloon 26 is **connected to the first sleeve 25 (figure 6)** and the second end of the Williamson balloon 26 is **connected to the second sleeve 27 (figure 6)**.

Williamson FIG. 5 is a view of the individual items that are shown in their assembled state in Williamson FIG. 6. Reference to Williamson FIG. 6 reveals that neither the first end of the balloon 26 nor the second end of the balloon 26 is connected to the **second sleeve 27**. Referring to the viewer's left in Williamson FIG. 6, the two ends of the balloon 26 terminate to form the tubular conduit 45 that defines the inner, elongated central channel 34 in the elastomeric sealing element 26 and are **attached to the first sleeve 25** that includes the flat circular flange 28, the cylindrical neck 29 and the annular rim 33. Referring to the viewer's right in Williamson FIG. 6, the two ends of the balloon 26 are overlapping one another and **attached to the first sleeve 25** between the cylindrical neck 29 and the annular rim 33. Thus, both ends of the Williamson balloon 26 are **only attached to the first sleeve 25**, and Williamson therefore fails to disclose a device that anticipates applicant's claim 1 or any claim dependent thereon.

Applicant therefore respectfully submits that claims 1-6, 13, 21 and 22 are patentable under 35 U.S.C. 102(b) over Williamson.

For the reasons explained below, applicant respectfully traverses the rejection of claim 7 under 35 U.S.C. 103(a) as being unpatentable over Williamson.

The deficiency in Williamson noted above precludes Williamson from rendering claim 7 obvious to the person of ordinary skill.

Applicant therefore respectfully submits that claim 7 is patentable under 35 U.S.C. 103(a) over Williamson.

For the reasons explained below, applicant respectfully traverses the rejection of claims 8, 9, 12 and 23 under 35 U.S.C. 103(a) as being unpatentable over Williamson in view of Kieturakis.

Kieturakis fails to compensate for the deficiency in Williamson noted above.

Applicant therefore respectfully submits that claims 8, 9, 12 and 23 are patentable under 35 U.S.C. 103(a) over Williamson in view of Kieturakis.

For the reasons explained below, applicant respectfully traverses the rejection of claim 14 under 35 U.S.C. 103(a) as being unpatentable over Williamson in view of Haber et al.

Haber et al fails to compensate for the deficiency in Williamson noted above.

Applicant therefore respectfully submits that claim 14 is patentable under 35 U.S.C. 103(a) over Williamson in view of Haber et al.

For the reasons explained below, applicant respectfully traverses the rejection of claims 16 – 18 under 35 U.S.C. 103(a) as being unpatentable over Williamson in view of Kieturakis and further in view of Haber et al.

Kieturakis and Haber et al fail to compensate for the deficiency in Williamson noted above.

Applicant therefore respectfully submits that claims 16 – 18 are patentable under 35 U.S.C. 103(a) over Williamson in view of Kieturakis and further in view of Haber et al.

For the reasons explained below, applicant respectfully traverses the rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Williamson in view of Mulhauser et al.

Mulhauser et al fails to compensate for the deficiency in Williamson noted above.

Applicant therefore respectfully submits that claim 15 is patentable under 35 U.S.C. 103(a) over Williamson in view of Mulhauser et al.

For the reasons explained below, applicant respectfully traverses the rejection of claims 19 and 20 under 35 U.S.C. 103(a) as being unpatentable over Williamson in view of Kieturakis and Haber et al and further in view of Salama.

Kieturakis, Haber et al and Salama fail to compensate for the deficiency in Williamson noted above.

Applicant therefore respectfully submits that claims 19 and 20 are patentable under 35 U.S.C. 103(a) over Williamson in view of Kieturakis and Haber et al and further in view of Salama.

For the reasons explained below, applicant respectfully traverses the rejection of claims 24 and 25 under 35 U.S.C. 103(a) as being unpatentable over Williamson in view of Kieturakis and further in view of Kim.

Kim and Kieturakis fail to compensate for the deficiency in Williamson noted above.

Applicant therefore respectfully submits that claims 24 and 25 are patentable under 35 U.S.C. 103(a) over Williamson in view of Kieturakis and further in view of Kim.

Applicant respectfully requests reconsideration and reexamination of claims 1 – 9 and 12 – 25, as presented herein, and submits that these claims are in condition for allowance and should be passed to issue.

If any fee or extension of time is required to obtain entry of this Amendment, the undersigned hereby petitions the Commissioner to grant any necessary time extension and authorizes charging Deposit Account No. 04-1403 for any such fee not submitted herewith.

Respectfully submitted,

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DATE:

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